



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/645,594	08/25/2000	Malcolm King	11157-14	4598

1059 7590 01/24/2002

BERESKIN AND PARR
SCOTIA PLAZA
40 KING STREET WEST-SUITE 4000 BOX 401
TORONTO, ON M5H 3Y2
CANADA

EXAMINER	
WELLS, LAUREN Q	
ART UNIT	PAPER NUMBER

1619

DATE MAILED: 01/24/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/645,594	KING, MALCOLM
	Examiner Lauren Q Wells	Art Unit 1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 06 December 2001.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-19,27 and 28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-19,27 and 28 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.

4) Interview Summary (PTO-413) Paper No(s). _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

DETAILED ACTION

Claims 1-19 and 27-28 are pending. Claims 20-26 were cancelled by the Amendment received December 6, 2001, Paper No. 10.

Response to Applicant's Arguments/Amendment

The Applicant's arguments filed December 6, 2001 (Paper No. 9) to the rejection of claims 1, 7 and 10 made by the Examiner under 35 USC 112 have been fully considered and deemed not persuasive.

The Applicant's arguments to the rejection of claims 1-28 made by the Examiner under the judicially created doctrine of double patenting have been fully considered and deemed persuasive. Therefore, the said rejections are hereby withdrawn.

The Applicant's cancellation of claims 20-26 overcomes the 35 USC 102 rejection made by the Examiner.

Applicant's arguments to the rejection of claims 1-28 made by the Examiner under 35 USC 103 have been fully considered but are moot in view of the new ground(s) of rejection.

The objections to the declaration are hereby withdrawn, as Applicant's arguments are persuasive.

112 Rejection Maintained

The rejection of claims 1, 7 and 10 under 35 U.S.C. 112 is MAINTAINED for the reasons set forth in the Office Action mailed June 6, 2001, Paper No. 7, and those found below.

The Applicant argues that the terms "decreasing" and "improving" are sufficiently clear. This argument is not persuasive. The present invention provides no means of quantitatively

substantiating the term "decreasing" and "improving". Thus, these terms are relative and therefore, vague and indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19 and 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Speert et al. (5,514,665) in view of Beller et al. (Am. J. Obstet. Gynecol.) in further view of Ahmed (5,980,865) and Kennedy et al. (WO 91,15216).

Speert et al. a method of preventing or reducing the risk of infection by bacterial pathogens in vivo by administering compositions of dextran or dextran sulfate. Disclosed is the effect of dextran sulfate on the adhesion of *P. aeruginosa*, an infection commonly manifested in cystic fibrosis patients, to buccal epithelial cells. Topical administration and aerosol administration of dextran sulfate is disclosed. Further disclosed are pharmaceutical carriers and concentrations of dextran sulfate in composition. Speert et al. fails to teach the molecular weight of dextran, a method of clearing mucus, methods of diagnosing, and methods of determining dosage. See Col. 1, line 20-Col. 12, line 11.

Beller et al. teach the biochemical identification of the mucus of pseudomyxoma peritonei as the basis for mucolytic treatment. The reference teaches administration of dextran sulfate to patients suffering from excessive mucus in their digestive tract, wherein dextran sulfate lyzes and clears the mucus from the digestive tract. See pg. 970-971.

Ahmed teaches a method of treating a mammalian patient suffering from allergic reactions, airway hyperresponsiveness, or inflammatory reactions comprising administering a pharmaceutical composition containing 0.005 to 1 mg/kg of ultra low molecular weight heparins or other sulfated polysaccharides having average molecular weights of about 1,000-3,000. Disclosed forms include topical and aerosol compositions. See Col. 2, line 49-Col. 4, line 34; Col. 8, line 20-Col. 12, line 67; Col. 17, line 36-Col. 20, line 8.

Kennedy et al. teach a medicament and method for treatment of human leucocyte-mediated diseases comprising the administration of a poly-sulfated polysaccharide to a host. Dextran sulfate is disclosed as a poly-sulfated polysaccharide. Molecular weights of the poly-sulfate polysaccharides are disclosed as less than 100,000 and molecular weights of 5000 and 8000 are exemplified for dextran sulfate. See pg. 4, line 21-pg. 9, end; pg. 11, line 8-line 13; pg. 18-pg. 19.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Beller with the invention of Speert and obtain a method of decreasing viscoelasticity of respiratory tract mucus by administering an effective amount of charged dextran because a) Speert and Beller both teach dextran sulfate as active agents; b) Speert teaches dextran sulfate as a known anti-coagulant, though he does not specifically define the anti-coagulant properties of dextran sulfate in regards to mucus; d) Speert teaches dextran sulfate for the treatment of bacterial pathogens commonly seen in cystic fibrosis; c) cystic fibrosis is characterized by the production of abnormally viscous mucus by the affected glands, usually resulting in

chronic respiratory infections and impaired pancreatic function. Also called *mucoviscidosis*.¹; thus, since Beller utilizes dextran sulfate for decreasing the viscoelasticity of mucus in the digestive tract (aka lysis and clearing mucus) one would expect dextran sulfate to have similar effects in the respiratory tract; hence, the teaching of dextran sulfate for decreasing the viscoelasticity of mucus in the respiratory tract would be within the skill of one in the art, especially since Speert teaches dextran sulfate as having anti-coagulant properties and for use with cystic fibrosis.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the teachings of Ahmed and Kennedy in the invention of the combined references and obtain dextran sulfate with a molecular weight of 500 to 5000 because a) Kennedy and the combined references teach dextran sulfate for the treatment of respiratory infections; b) and Kennedy teaches that the molecular weights of dextran sulfate, to be used in such a capacity, as being less than 10,000 and the combined references teach dextran sulfate as having a molecular weight of less than 10,000; c) Kennedy teaches the interchangeability of heparin sulfate and dextran sulfate in treating bacterial respiratory disorders; d) Ahmed teach ultra-low molecular weight (ULMW=1,000-3,000) sulfated heparins for the treatment of respiratory tract disorders.

The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

¹ *The American Heritage® Dictionary of the English Language, Third Edition* copyright © 1992 by Houghton Mifflin Company. Electronic version licensed from INSO Corporation; further reproduction and distribution restricted in accordance with the Copyright Law of the United States. All rights reserved.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on December 6, 2001 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on T-F (6-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Art Unit: 1617

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw
January 16, 2002



DAMERON L. JONES
PRIMARY EXAMINER